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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/561,800

11/13/2006

Dieter Reif

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EXAMINER

BERRIOS, JENNIFER A

ART UNIT

PAPER NUMBER

4121

MAIL DATE

DELIVERY MODE

02/25/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/561,800	Applicant(s) REIF ET AL.	
	Examiner Jennifer A. Berrios	Art Unit 4121	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/21/2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/3/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

Claims 1-21 are currently pending.

Election/Restriction

Applicant's election with traverse of Group I in the reply filed on 1/21/2009 is acknowledged. The traversal is on the ground(s) that Group I and I do in fact share a special technical feature and are in conformity with PCT Rule 13.1. This is not found persuasive because as demonstrated in the restriction requirement the special technical feature of instant claim 1 does not present a contribution over the prior art WO02/083194.

1. The requirement is still deemed proper and is therefore made FINAL.
2. Claim 21 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group II, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 1/21/2009.

Priority

This application is a 371 of PCT/EP04/06947 (filed: 6/25/2004)

This application claims the benefit of priority under 35 USC § 119 of German foreign application 103 28 892.9 (filed: 6/26/2006).

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- a. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Germany on 6/26/2003
3. Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a certified English translation of the foreign application must be submitted in reply to this action. 37 CFR 41.154(b) and 41.202(e).

Failure to provide a certified translation may result in no benefit being accorded for the non-English application.

As such claims 1-20 receive the priority date of 6/25/2004.

Claim Rejections – 35 USC § 112 – 2nd Paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. The phrase "substantial extent, and especially to an extent of at least" in claim 5 is a relative term which renders the claim indefinite. The phrase "substantial extent, and especially to an extent of at least" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. For

purpose of examination the Examiner will read the claim as consisting of a substantial amounts of calcium phosphate, necessary for bone formation. "

Claim Rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 7 and 17 are rejected under 35 USC 102(b) as being anticipated by WO 02/083194, provided by applicant, (pub. date: 10/24/2002; filing date: 4/12/2002). WO 02/83194 teaches a biostructure for implantation, which includes an internal microstructure, mesostructure and/or macrostructure (abstract). The biostructure may be made of powder particles (granules) whose average particle diameter is from 10-50 microns, however the size can be as large as 300 microns (pg 9, lines 7-10). The embodiment of the invention of WO 02/83194 further includes a bimodal pore size distribution where in the pore size distribution range from 2-200 microns, with a peak between 10-15 microns and larger than 25 (pg 120, claims 3 and 19). It further teaches that the biostructure matrix material is hydroxyapatite or tricalcium phosphate or any other calcium phosphate resorbable substance (pg 135, claim 111) and is referred to as isotropic (pg 10, lines 12-13). The biostructure may also contain one or more bioactive substances selected from antibiotics, growth promoting substances and others (pg 134, claim 103).

Claim Rejection – 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 3-4 are rejected under 35 U.S.C 103(a) as being unpatentable over WO 02/083194, in view of WO 92/21302, provided by Applicant, (pub. Date: 12/10/1992).

Instant claims 3-4 teach the bone formation agent of claim 1 to have three discrete pore sizes (I-III) ranging from: (I) 5-10 μm , (II) 10-100 μm and (III) 100-500 μm , with (I) ranging from 20-40% by volume, (II) ranging from 5-40% and (III) ranging from 1-40% by volume, the overall porosity not exceeding 85% by volume.

WO 02/083194 fails to teach all the limitations of instant claims 3-4.

WO 92/21302 teaches an implant made of a porous, non-toxic material with a total porosity larger than 5% but not greater than 80% by volume. The implant is characterized in that it has three distinct pore sizes: .1-10 μm occupy 10-80% by volume; 10-50 μm occupy not more than 5% and 50-500 μm occupy from 5-40%.

It would have been prima obvious to one of ordinary skill in the art at the time the invention was made to combine the teaching of WO 02/083194 and WO 92/21302. One would be motivated to do so because by having a distribution of pore sizes, in this case three, one can combine a high strength and a capacity to meet high requirements as to

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a favorable situation for bone ingrowth as well as tissue ingrowth with an integrated interaction between soft and hard tissues (WO 92/21302, pg 2, lines 22-26). Finally one of skill in the art would expect to be successful because both references teach porous biostructures, which comprise calcium phosphate, for implantation that comprise a plurality of pore size distributions.

Claims 5, 8-16 and 18-20 are rejected as being unpatentable over WO 02/083194 in view of WO 92/21302, as applied to claims 1 and 3-4 above, and further in view of US 6,521,246 (issued: 2/18/2003, filed: 12/15/2001).

Instant claim 5 further limits claim 1 by teaching that the bone formation agent is characterized by the fact that the calcium phosphate consists of a substantial amount of alpha-tricalcium phosphate, beta-tricalcium phosphate among other or mixtures thereof.

Claims 8-9 teach that the bone formation agent is characterized in the form of a granulate, has a substantially non-uniform and/or uniform geometric shape. Claim 10 limits the granulate to a spherical shape. Claim 13 and 19 teaches the bone formation agent as taught by claim 1 to be in the form of a shaped body having a defined geometric shape, preferably a cube, cuboid, cylinder or wedge.

WO 02/083194 and WO/ 9221302 while teaching the bone formation agent, fails to teach the characteristics of the granulates of the bone formation agent.

The '246 patent teaches inorganic shaped bodies useful for bone grafting materials, cell growth scaffolds, drug delivery and more. It also teaches the methods of producing said inorganic bodies (column 1, lines 24-28). The '246 patent also teaches

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that these inorganic bodies can be formed into virtually any geometric shape (column 4, lines 2-3), although a uniform one is preferable, as suggested by the '246 patent claims 1, 14 and 22. The '246 patents goes on to teach that the uniform shaped body comprising meso-, micro-, and macroporous calcium phosphate, which comprises beta-tricalcium phosphate, is in the shape of a tube, block or sphere. The '246 fails to explicitly state the amount of beta-tricalcium phosphate present in the inorganic material, but one of skill in the art would understand that a substantial amount necessary to perform the functions (bone grafting, cell growth, etc) were present.

It would have been *prima face* obvious to one of ordinary skill in the art to combine the teachings of the '246 patent with teaching of WO 02/83194 and WO 92/21302. One of skill in the art would be motivated to do so the embodiments of the '246 patent (beta-tricalcium and the geometric shapes of the inorganic body) provide a large varieties of shaped bodies that can find wide used in surgery, laboratory and industrial processes (abstract of the '246 patent). Finally, one of ordinary skill in the art would be motivated to combine the above teaches, because all teach biostructures with a distribution of pore sizes (2-3) and the biostructure comprising tricalcium phosphate, for the use of bone grafting, tissue growth, and more.

The references described above do not teach the limitation of instant claims 11-12, 14-16, 18 and 20. However these limitation further describe specific properties of the bone formation agent. Although specific reference isn't made to the characteristics of instant claims 11-12, 14-16, 18 and 20, it is expected that the bone formation agent

taught by references WO 02/083194, WO/ 9221302 and the '246 patent, to have the characteristics taught by the instant claims.

Claims 1 and 6 are rejected under 35 U.S.C 103(a) as being unpatentable over WO 02/083194 (pub. date: 10/24/2002; filing date: 4/12/2002), in view of Trisi *et al* (J Periodontics Restorative Dent 2003: 23:69-77).

Claim 6 teaches that the bone formation agent of instant claim 1 is tricalcium phosphate, specifically beta-tricalcium phosphate having a phase purity of $\geq 99\%$ by weight.

WO 02/083194 fails to teach the limitation of claim 6.

Trisi *et al* teaches the effect of pure phase beta-tricalcium phosphate in bone regeneration. It teaches that pure phase beta-tricalcium phosphate is characterized by a ≥ 99 purity of the beta isomer. This material is more rapidly and predictably resorbed and replaced by newly formed bone without any residue (pg 70, paragraph 4).

It would have been *prima face* obvious to one of ordinary skill in the art to combine the teachings of Trisi *et al* and WO 02/083194. One of skill in the art would have been motivated to do so because by using pure phase beta-tricalcium phosphate in the bone formation agent, the agent would be more rapidly resorbed and replaced by newly formed bone, therefore enhancing the function of the bone formation agent. Finally one of skill would expect to be successful because both teach agents used for bone formation and regeneration that comprise mainly calcium phosphate.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer A. Berríos whose telephone number is (571)270-7679. The examiner can normally be reached on M-F 8:00am-5:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on (571) 272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

J.B.

/Patrick J. Nolan/

Supervisory Patent Examiner, Art Unit 4121